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ON

**“REEXAMINING THE SUBSTANDARD QUALITY OF INDIAN HEALTH CARE IN
THE GREAT PLAINS”**

BEFORE THE

UNITED STATES SENATE COMMITTEE ON INDIAN AFFAIRS

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“Reexamining the Substandard Quality of Indian Health Care in the Great Plains”
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Chairman Barrasso, Vice Chairman Tester, and members of the Committee, thank you for the invitation to discuss the Centers for Medicare and Medicaid Services’ (CMS’) work to monitor the quality of health care provided at Indian Health Service facilities. CMS is committed to ensuring the safety of the millions of Americans who rely on the U.S. health care system every day. To monitor the safety of care provided throughout the country, CMS requires that all facilities seeking participation in Medicare and Medicaid comply with basic health and safety requirements set forth in the Medicare Conditions of Participation (CoPs). The Survey and Certification process is used by CMS to assess compliance with these requirements. It is CMS’ duty to provide objective, onsite assessments of the quality and safety in health care facilities, properly identify any deficiencies, and require that timely corrections are made to any identified deficiencies. We understand that our responsibilities and enforcement requirements may bring challenges to health care facilities, and CMS is committed to working with facilities and providers in good faith as they strive to deliver safe, high quality care.

CMS has fulfilled this role in our work with Indian Health Service (IHS) facilities in the Great Plains area. CMS surveyors have conducted numerous recertification and complaint surveys at IHS facilities, required that corrective action be taken, and monitored their progress in addressing identified deficiencies. Also, in an effort to help IHS hospitals better understand the requirements of the CoPs and address quality deficiencies, CMS has provided considerable technical assistance to a number of IHS hospitals. For example, CMS encouraged administrators at IHS hospitals to participate in compliance training, and has trained 565 IHS staff to date as a part of that effort. CMS also provided onsite technical assistance to staff at the Pine Ridge hospital to help staff understand the quality and safety expectations embodied in CMS regulations. In addition, Quality Improvement Organizations (QIOs), under contract with CMS, provided technical assistance at IHS hospitals (specifically Winnebago) with regard to methods that the hospitals could use to meet Plan of Correction (PoC) requirements. These CMS efforts were intended to support and bolster the IHS’ own system-wide efforts to provide technical assistance, training, and personnel actions that might address quality of care issues.

CMS Survey and Certification

CMS maintains oversight for compliance with the Medicare health and safety standards for laboratories, acute and continuing care providers (including hospitals, nursing homes, home health agencies, end-stage renal disease facilities, hospices, and other facilities serving Medicare and Medicaid beneficiaries). CMS' Medicare CoPs for hospitals set out quality and safety standards on a wide range of topics such as emergency treatment, infection control, medication management, credentialing and privileging of physicians, and responsibilities of the hospital's governing body to ensure safe care.

Generally, State survey agencies (SAs)¹ conduct hospital recertification surveys every three years on behalf of CMS to assess facility compliance with Medicare CoPs and the Emergency Medical Treatment and Labor Act (EMTALA) requirements. However, CMS surveyors may also conduct these surveys, as is the case with IHS facilities. EMTALA requirements impose specific obligations on Medicare-participating hospitals that offer emergency services to screen, treat, or appropriately transfer patients, regardless of their ability to pay. Surveyors also investigate complaints alleging hospital noncompliance with CoPs. A hospital cannot participate in Medicare unless it meets each and every CoP. As part of the CoPs, surveyors conduct Life Safety Code surveys to ensure the safety of patients from fire, smoke and other environmental hazards. These standards apply to all Medicare hospitals to ensure basic health and safety standards. Under section 1865 of the Social Security Act, CMS has also approved four accrediting organizations (AOs) for hospitals whose standards and survey processes are determined to be equivalent to those of CMS. CMS deems a hospital's accreditation by an approved AO to be sufficient for Medicare certification. The AOs conduct recertification surveys at least once every three years for hospitals. CMS retains the right to conduct complaint investigations of accredited facilities, and remove a provider's deemed status if CMS finds serious deficiencies. CMS also conducts validation surveys of a sample of accredited hospitals to check on the adequacy of the AO surveys.

¹ For IHS facilities, Accrediting Organizations (AOs) or Federal surveyors conduct recertification and complaint reviews. This is due to their status as a federal facility.

The survey and certification process includes, but is not limited to, conducting surveys to determine whether health care entities comply with Medicare CoPs or requirements; and conducting enforcement actions when these entities are found to be out of compliance with the Medicare CoPs. For example, during a hospital survey, the surveyors examine the hospital's health records, interview staff and patients and observe the processes of care. This includes observing doctors and nurses as they provide emergency services to assess the facility's ability to adequately provide emergency screenings and services.

As a result of the survey, the SA or CMS may find the hospital in violation of Medicare's CoPs, EMTALA, or find that the hospital has deficiencies so serious that they constitute an immediate and serious threat to the health and safety of patients, referred to as immediate jeopardy (IJ). Hospitals have 23 days to correct IJ violations and 90 days to correct other CoP and EMTALA violations to avoid termination from the Medicare program.

If Deficiencies are Found

If any deficiencies are found during the survey, the SA certifies that the facility is non-compliant and recommends termination to the CMS Regional Office (RO). The RO then sends the institution a "Statement of Deficiencies" outlining deficiencies that were identified during the survey. CMS follows a specific timeline for every hospital where deficiencies are found.² First, the institution is given five calendar days to respond to deficiencies at the IJ level or 10 calendar days in which to respond to less serious CoP or EMTALA deficiencies. The response must include a PoC for each cited deficiency, which is included on the form containing the statement of deficiencies. Once a facility has made a credible allegation of compliance³, surveyors conduct a revisit to determine whether compliance with the CoP or acceptable progress towards compliance has been achieved. Only two revisits are generally permitted in the hospital setting; one within 45 calendar days and one between the 46th and 90th calendar days. If compliance is achieved, the facility goes back to the regular certification schedule.

If compliance has not been achieved, the SA certifies that the facility remains non-compliant. Within 65 calendar days following the date of survey, the RO determines whether survey

² https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationEnforcement/Downloads/Schedule_of_Termination_Procedures.pdf

³ Credible allegations of compliance include, a statement or documentation that is realistic in terms of the possibility of the corrective action being accomplished, and that indicates resolution of the problem.

findings continue to support a determination of noncompliance. If all requirements are met by the hospital, the hospital returns to its normal recertification schedule.

If the determination of noncompliance continues, the RO sends an official termination notice by the 70th calendar day to the facility, the public, and the State Medicaid Agency if the facility also participates in Medicaid. The termination generally takes effect by the 90th calendar day if compliance has not been achieved. Termination can take effect in fewer than 90 days if all required procedures are completed. CMS sometimes extends the prospectively scheduled termination date if CMS requires more time to schedule or complete a revisit survey that is necessary to confirm that corrective action has restored the hospital to compliance with the CoPs, or if there are very unusual circumstances such as the need to make alternate arrangements for care of patients in remote areas.

If an adverse action, such as a termination, is likely to be initiated against a Medicare participating provider or supplier, the CMS RO follows procedures outlined in the State Operations Manual.⁴ We note that every facility faced with termination from Medicare participation is provided with a full opportunity to take necessary remedial action and demonstrate compliance with the CoPs before the prospectively-scheduled Medicare termination date. In addition, if the institution disagrees with the finding of noncompliance, it may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board within 60 calendar days of the final CMS notice of termination. Finally, any provider that CMS has involuntarily terminated from Medicare participation has the right to apply for reinstatement at any time. To be reinstated, subsequent onsite surveys must confirm not only that the provider has restored its services to compliance with the CoPs, but that the provider demonstrates reasonable assurance that the deficiencies which led to involuntary termination are not likely to recur.

We appreciate that, in some circumstances, Medicare termination of a provider may cause or increase access to care problems for beneficiaries. While such considerations do not influence in any way the proper identification of quality or safety deficiencies, we can consider such factors in the selection of enforcement methods. In an effort to balance patient access to care while ensuring high quality health care, CMS considers factors such as patient driving times to the next

⁴ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c03.pdf>

nearest facility, specialized services provided at the nearest facility, and the identified facility's ability to achieve and maintain substantial compliance with CoPs. If patient access to care may be greatly affected, CMS may look into additional options to help preserve beneficiary access to care and help the hospital meet CoP and EMTALA requirements. An example that CMS has used in rare but serious access to care situations is a Systems Improvement Agreement (SIA). An SIA is an agreement, voluntarily entered into by CMS and a hospital that obliges the hospital to engage in a specified regimen of quality improvement, and make significant investments in improving the quality of care, in exchange for more time to make needed systemic improvements before Medicare termination would take effect. All of these requirements and timelines are available for public review in the State Operations Manual and in CMS regulations.⁵ CMS, SA, and AO conduct CoP and EMTALA education and outreach to hospitals through Open Door Forums, and additional assistance is also provided to facilities from Quality Improvement Organizations (QIOs).

Both private and IHS hospitals in the Great Plains area face a number of challenges including their location in rural areas and difficulty attracting qualified administrators and physicians to work in their facility. Due to these and numerous other factors, three IHS hospitals, as described below, have had challenges meeting CoP and EMTALA requirements in recent years.

Issues Identified at the Winnebago Indian Health Service Hospital

CMS surveyors have been investigating and monitoring complaints made regarding Winnebago Indian Health Service Hospital. CMS conducted a complaint survey of the hospital on April 8, 2011 and found the hospital to be in violation of various Medicare CoPs. The deficiencies included failure to ensure there were systems in place to inform patients of their rights, to promptly investigate and respond to patient grievances, to ensure patients have information necessary to make informed consent regarding their care, and to investigate allegations of patient abuse to assure patients are protected. Due to the importance of these findings, the hospital was notified that a Medicare survey would be conducted to assess compliance with all CoPs, not just those that had been the subject of the complaint.

⁵ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html>. The SIA content for organ transplant programs may be found at 42 CFR 488.61(h).

CMS subsequently conducted a full recertification survey on October 14, 2011 and found the hospital to be out of compliance with nine CoPs: compliance with Governing Body responsibilities, Patients' Rights, Quality Assessment and Performance Improvement, Medical Staff, Nursing Services, Radiological Services, Infection Control, Organ/Tissue/Eye, and Emergency Services. The hospital was notified of CMS' intention to terminate the hospital's Medicare agreement on January 16, 2012 if it did not correct these violations. A variety of plans of correction and improvement efforts ensued, including extensive direct assistance from the Nebraska QIO, under contract with CMS, throughout 2013 and 2014.

In a response to another complaint filed, the hospital was surveyed on April 25, 2014, and found to be out of compliance with CoPs concerning Nursing Services, specifically related to failure to assure the nursing staff were adequately trained and possessed the necessary knowledge and skills to ensure patients were provided safe and appropriate care. Surveyors determined that this noncompliance placed patients in IJ. CMS provided Winnebago with a termination date of May 18, 2014. Surveyors conducted a revisit survey on May 15, 2014 that found Nursing Services remained out of compliance. In response to IHS requests for additional time, CMS conducted additional surveys and extended the Medicare termination date.

An additional revisit survey, conducted on July 17, 2014, found the hospital remained noncompliant concerning Nursing Services and found that Emergency Services were also out of compliance. These concerns still constituted an IJ due to the survey's findings that the hospital failed to provide services, equipment, personnel and resources within timeframes that protect the health and safety of patient receiving medical care in the emergency department (ED); and that the hospital failed to maintain policies and procedures for emergency medical services provided to all patients who receive medical care in the ED.

An additional survey conducted on August 27, 2014 found the hospital to be out of compliance with EMTALA requirements. CMS determined that the EMTALA violation constituted an IJ, and also found continuing noncompliance with the CoP of Nursing Services and Emergency Services. Of the 25 medical records randomly selected from the ED log from March 2014 to August 2014, the hospital failed to provide adequate medical screening examinations to three patients and failed to provide stabilizing treatment within its capabilities to one patient.

Winnebago submitted a performance plan to stay the termination. As part of our responsibilities,

CMS scheduled a full Medicare survey before the hospital was scheduled to be terminated from Medicare on November 6, 2014. The termination date was later extended to December 5, 2014 to allow surveyors time to complete a survey report.

On November 6, 2014, CMS surveyors conducted the full Medicare survey at the hospital to assess compliance with all the applicable Medicare CoPs and to assess that status of the noncompliance findings of the previous surveys. During this survey, the IJ findings cited in previous surveys were deemed removed and the previous noncompliance findings were determined to have been corrected. However, the hospital was found to be out of compliance with other Conditions concerning their Governing Body, Nursing Services, Food and Dietetic Services and Emergency Services. Although the deficiencies cited were serious, they did not constitute an IJ to the health and safety of patients. On November 21, 2014, CMS notified the hospital of these changes and extended the termination date to April 30, 2015 to allow a revisit survey. On April 23, 2015, the termination date was extended to June 15, 2015, to allow the revisit to occur.

CMS Federal surveyors then conducted revisit and complaint surveys on May 14, 2015 and found that the hospital was noncompliant with seven CoPs including: Governing Body, Nursing Services, Outpatient Services, Emergency Services, Appropriate Medical Screening Examination, Stabilizing Treatment, and Appropriate Transfer. The noncompliance was found to constitute an IJ. Because of ongoing noncompliance since 2011 and repeated IJ citations, despite technical assistance from CMS and the Nebraska QIO and repeated PoCs prepared by the hospital, it was determined no further extensions would be granted and that the hospital would be terminated July 23, 2015. On July 8, 2015, CMS issued notice of final termination of Medicare participation to the hospital, effective July 23, 2015, with concurrent newspaper notice. The hospital has appealed the termination. The IHS has continued to work with the hospital and Tribal officials, and has engaged a consultant firm to assist the hospital and facilitate resolution of the problems. CMS stands ready to respond to a request from the hospital for a survey that might start a reinstatement process if the hospital is found to be in compliance with the CoPs.

Issues Identified at the Rosebud Indian Health Service Hospital

To investigate an EMTALA violation complaint, Federal surveyors conducted a recertification survey at Rosebud Indian Health Service Hospital on November 16-19, 2015 and a Life Safety

Code Recertification Survey on November 17-18, 2015. Based on the survey findings, it was found that the hospital was not in compliance with all of the Medicare CoPs for hospitals and that deficiencies put patients in IJ, particularly related to risk of inappropriate care in the ED. As a result, CMS notified the hospital of the intent to terminate on December 12, 2015 if the hospital did not prepare a PoC and correct these violations. The hospital placed its ED on diversion. IHS later notified CMS that it would temporarily close the ED and CMS then removed the IJ. Following this closure, the IJ was removed, giving the facility until February 17, 2016 to address its remaining ED and CoP compliance issues. The hospital has agreed not to reopen the ED without seven days prior notice to CMS to allow CMS time to conduct an onsite survey of the ED. CMS will also reschedule a revisit survey once the ED has reopened.

On January 5, 2016, CMS also found that Rosebud Hospital was in violation of EMTALA requirements, specifically, failure to provide appropriate medical screenings and stabilizing treatment to patients presenting to the emergency department. On January 6, 2016, CMS sent the hospital a notice of intent to terminate Medicare participation due to the EMTALA deficiency. The hospital's PoC for the EMTALA violation is due to CMS on March 15, 2016 to avoid a termination date of May 19, 2016.

Issues Identified at the PHS Indian Hospital at Pine Ridge

On October 29, 2015, following a complaint survey of PHS Indian Hospital at Pine Ridge, federal surveyors identified that the hospital was out of compliance with three CoPs and was in violation of EMTALA. CMS identified concerns with the hospital's Quality Assessment and Performance Improvement program, which is the hospital's system for tracking, analyzing and developing plans to address significant issues. As a result, CMS gave the hospital until January 27, 2016 to correct these violations to avoid termination. CMS received and approved the hospital's PoC.

On January 14, 2016, federal surveyors completed a revisit of this hospital. They found the hospital in compliance with the CoPs, but still in violation of EMTALA. CMS issued a termination date of February 23, 2016 for the EMTALA violation. The hospital will have one more opportunity to demonstrate compliance with the EMTALA requirements prior to this date. CMS expects the hospital to submit a PoC prior to February 23, 2016. If the PoC is accepted, another revisit would occur.

Conclusion

CMS remains diligent in our duties to monitor every hospital participating in Medicare to help ensure patient safety and access to care across the country. CMS surveyors have relied on longstanding policies when engaging with IHS facilities in the Great Plains area. It is our obligation to ensure all health care facilities are safe and can meet patient needs. CMS and QIOs have provided numerous hours of technical assistance to IHS facilities regarding quality improvements and deficiencies. We will continue to work with IHS as these hospitals strive to make improvements and to make sure patients are receiving quality health care services. We are hopeful that these hospitals will soon be able to come in to compliance with all relevant requirements and continue to provide much-needed care to patients in the Great Plains area. We appreciate the Committee's interest, and I would be pleased to address any questions you may have.